

Message Text

UNCLASSIFIED

PAGE 01 STATE 015092 POSS DUPE
ORIGIN HEW-06

INFO OCT-01 ISO-00 OES-06 EA-09 NEA-10 EUR-12 EB-08 COME-00
/052 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.:CCK
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: BROYSTER
EUR/EX:JLTULL(INFO)
EA/J:RACHRISTENSON(INFO)

-----241906Z 022892 /53

R 241428Z JAN 77
FM SECSTATE WASHDC
TO AMEMBASSY PARIS
AMEMBASSY TEL AVIV
AMEMBASSY ROME
AMEMBASSY TOKYO
AMEMBASSY LONDON

UNCLAS STATE 015092

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, FR, IS, IT, JA, UK

SUBJECT: POSSIBLE NON-STERILITY OF MEDICAL DEVICE
(RECALL T-028-7)

1. FDA ADVISES OF THE FOLLOWING RECALL:

PRODUCT: PERCUTANEOUS CARDIOVASCULAR CATHETER INTRODUCER
8.5CM IN LENGTH WITH A 17 GAUGE NEEDLE. PRODUCT IS A
STERILE, RX, SURGICAL INSTRUMENT WHICH IS USED TO INTRODUCE
CATHETERS INTO ARTERIES OR VEINS DURING CARDIOVASCULAR AND
RELATED SURGERY. THE INTRODUCER/NEEDLE ASSEMBLY HAS A POLY-
SHIPPING TUBE OVER THE NEEDLE END. THIS ASSEMBLY IS THEN
PLACED INSIDE OF A POLY AND WHITE PAPER STERILIZING POUCH.

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A YELLOW AND WHITE INSTRUCTION SHEET IS INCLUDED WITH EACH
UNIT AND READS IN PART, "XXX EDSLAB MODEL 9701 XXX NON-
PYROGENIC, STERILE-SINGLE USE XXX PERCUTANEOUS CARDIO-
VASCULAR CATHETER INTRODUCER XXX CAUTION STATE (CA) AND
FEDERAL LAW RESTRICTS THIS PRODUCT TO SALE BY OR ON THE
ORDER OF A PHYSICIAN XXX EDWARDS LABORATORIES, DIVISION OF
AMERICAN HOSPITAL SUPPLY CORPORATION, SANTA ANA, CALIFORNIA

92705 XXX".

LOT NUMBER INVOLVED: LOT NUMBER 4H375 OF MODEL 9701. THE
4 EQUALS THE YEAR MANUFACTURED I.E., 1974, H EQUALS THE
MONTH I.E., AUGUST, 375 EQUALS A SEQUENTIAL BATCH NUMBER.

MANUFACTURER/RECALLING FIRM:

EDWARDS LABORATORIES
DIVISION OF AMERICAN HOSPITAL SUPPLY CORPORATION
17221 RED HILL AVENUE
SANTA ANA, CALIFORNIA 92705
TELEPHONE 714-557-8910

2. REASON FOR RECALL: THE FIRM STATES THAT A SMALL
NUMBER OF UNITS WITHIN THIS LOT MAY HAVE BEEN RELEASED
PRIOR TO FINAL STERILIZATION. A HOSPITAL COMPLAINT OF
SUSPECTED NONSTERILITY OF THE PRODUCT LOT RESULTED IN FDA
ANALYSIS OF THE SAMPLE WHICH SHOWED MOLD GROWTH. NO
INJURIES OR DEATH HAVE BEEN ASSOCIATED WITH THE PRODUCT
LOT.

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO
DETERMINE IF THEY HAVE RECEIVED RECALL LETTER DATED 30
NOVEMBER 1976 IN WHICH FIRM STATES THEIR ASKING CONSIGNEES
TO RECALL THE PRODUCT LOT IN QUESTION. ANY QUESTIONS CON-
SIGNEES MAY HAVE REGARDING THIS RECALL SHOULD BE DIRECTED
TO THE FIRM.

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4. FOREIGN CONSIGNEES AS FOLLOWS:

ETABLISSEMENTS PAUL LOUIS	SCIENTIFIC PRODUCTS INC.
14 16 18 RUE PAUL PAINLEY	SANKAIDO BLDG, S-13
PARC MODERNE D'ENTREPRISES	AKASAKA, CHOME MINETO-KU
FRANCE	JAPAN

ISRAMEDOOM LTD
P O B 4942
TEL-AVIV, ISRAEL

SECA S A S
VIA C RAVIZZA 3471
20149 MILANO
ITALY

EDWARDS LABORATORIES
DIV MCGAW SUPPLY LTD.
1601 MATHESON BLVD, ENGLAND

VANCE

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NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01-Jan-1994 12:00:00 am
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: MEDICAL EQUIPMENT, RECALLS
Control Number: n/a
Copy: SINGLE
Sent Date: 24-Jan-1977 12:00:00 am
Decaption Date: 01-Jan-1960 12:00:00 am
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01-Jan-1960 12:00:00 am
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1977STATE015092
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.:CCK
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Expiration:
Film Number: D770025-0551
Format: TEL
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1977/newtext/t19770124/aaaaauty.tel
Line Count: 118
Litigation Code IDs:
Litigation Codes:
Litigation History:
Locator: TEXT ON-LINE, ON MICROFILM
Message ID: 60162bd2-c288-dd11-92da-001cc4696bcc
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 3
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Retention: 0
Review Action: RELEASED, APPROVED
Review Content Flags:
Review Date: 23-Sep-2004 12:00:00 am
Review Event:
Review Exemptions: n/a
Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3520265
Secure: OPEN
Status: NATIVE
Subject: POSSIBLE NON-STERILITY OF MEDICAL DEVICE (RECALL T-028-7)
TAGS: OGEN, ETRD, TBIO, FR, IS, IT, JA, UK, FDA
To: PARIS TEL AVIV MULTIPLE
Type: TE
vdkgvwkey: odb://SAS/SAS.dbo.SAS_Docs/60162bd2-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009